

RCE
Notice of Allowability

Application No.

10/800,328

Examiner

Zachary C. Tucker

Applicant(s)

BRIGHT ET AL.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to RCE filed 26 May 2006.
2. ☒ The allowed claim(s) is/are 36-46.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

The following Examiner's Amendment was authorized by applicants' counsel, Ms. Mary J. Hosley, on 17 February 2006, during a telephone conversation with the undersigned examiner. In the remarks made by applicants' counsel accompanying the Request for Continued Examination to which this Office action is in response, applicants' counsel requests that the amendment filed under 37 C.F.R. 1.312 on 24 April 2006 be entered, though the Request for Continued Examination includes the amendments made in that '312 amendment. In the amendment filed under 37 C.F.R. 1.312 on 24 April 2006, the preliminary remarks, on page 1 of that correspondence, state that the amendment therein includes the Examiner's Amendment, referring to the Examiner's Amendment included in the Notice of Allowability mailed 28 February 2006. That amendment under 37 C.F.R. 1.312, however, does *not* incorporate the Examiner's Amendment. The amendment to claim 38, adding the phrase "in combination with a pharmaceutically acceptable carrier" was omitted from the '312 amendment, and the amendment to the abstract and pages 2 and 14 of the specification were also omitted.

Since it was clearly applicants' intention to incorporate the Examiner's Amendments into amendments filed subsequent to allowance, the examiner has reproduced the omitted parts of the original Examiner's Amendment, in this Examiner's Amendment, which was authorized by applicants' counsel prior to the first issuance of a Notice of Allowability (the amendments begin on the following page).

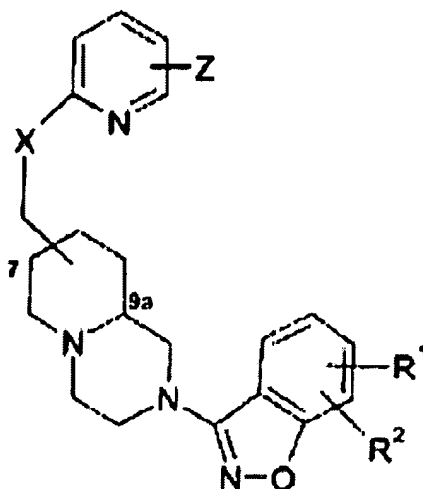
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IN THE SPECIFICATION -

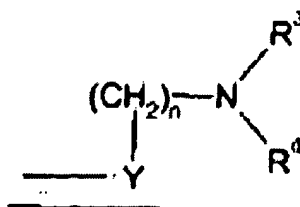
The abstract of the disclosure has been replaced with the following amended abstract:

Abstract of the Disclosure

An aminomethylpyridyloxymethyl/benzisoxazole substituted azabicyclic compound of formula I, a pharmaceutical composition comprising same, and a method of treating one or more CNS or other disorders, including concurrent treatment of disorders such as schizophrenia and depression, wherein formula I is



or a pharmaceutically acceptable salt thereof, wherein Z is

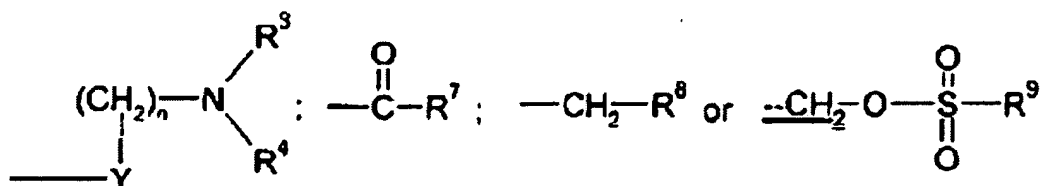


wherein Y is methylene; X is oxygen; n is 0; R¹ and R² are each hydrogen or halogen; and R³ and R⁴ together with the nitrogen atom to which they are attached form i) a saturated non-aromatic 3 to 7 membered monocyclic ring, said ring i) being unsubstituted or substituted with one or more (C₁-C₃)alkyl, (C₁-C₄)alkoxy(C₁-C₃)alkyl, or hydroxy groups.

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Please replace the paragraph at page 2, lines 19-23 with the following:

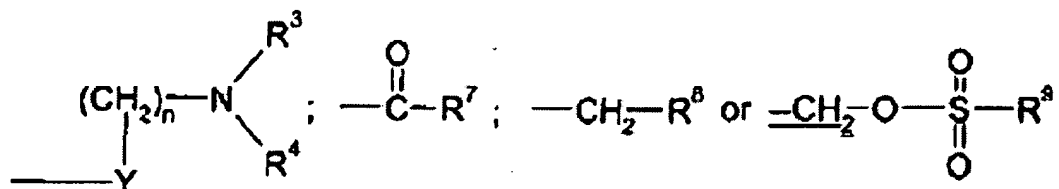
or the (R) or (S) enantiomer thereof, or the *cis* or *trans* isomer thereof, or a pharmaceutically acceptable salt, solvate or prodrug thereof or of any of the foregoing, wherein m is 0 or 1; Z is



wherein R⁷ is hydrogen or (C₁-C₃)alkoxy; R⁸ is hydrogen, hydroxy, or (C₁-C₃)alkoxy; and R⁹ is (C₁-C₃)alkyl;

Please replace the paragraph at Page 3, line 21 spanning to page 4, line 3 with the following:

or the (R) or (S) enantiomer thereof, or the *cis* or *trans* isomer thereof, or a pharmaceutically acceptable salt, solvate or prodrug thereof or of any of the foregoing, wherein Z is



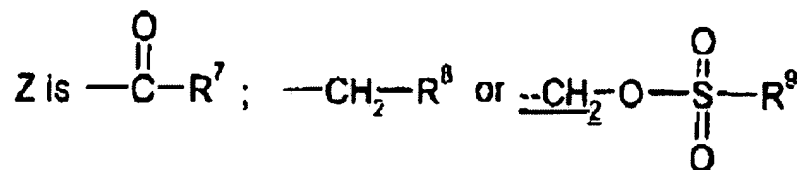
wherein R⁷ is hydrogen or (C₁-C₃)alkoxy; R⁸ is hydrogen, hydroxy, or (C₁-C₃)alkoxy; and R⁹ is (C₁-C₃)alkyl;

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Please replace the paragraph at page 14, lines 16-20 with the following:

as a racemate, or the (R) and (S) enantiomers thereof, or the *cis* and *trans* isomers thereof, wherein X is oxygen or NR, wherein R is hydrogen or (C₁-C₆)alkyl;

R¹ and R² are each independently as hereinbefore defined and



wherein R⁷ is hydrogen or (C₁-C₃)alkoxy; R⁸ is hydrogen, hydroxy, or (C₁-C₃)alkoxy; and R⁹ is (C₁-C₃)alkyl.

IN THE CLAIMS –

In claim 39, the phrase (including the comma at the beginning) “,in combination with a pharmaceutically acceptable carrier” has been inserted between the word “groups” and the period at the end of the claim.

end of amendments

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Request for Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 26 May 2006 has been entered.

Response to Amendment

As requested by applicants in the correspondence accompanying the RCE, pages 70-74 of the specification have been amended, and new claims 40-46 have been added.

Allowable Subject Matter

Claims 36-46 are allowed.

Reasons for allowance are as were indicated on page 5 of the Notice of Allowability mailed 28 February 2006.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

All Post-Allowance Correspondence concerning this application must be mailed to:
Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Or you can fax them to the Office of Patent Publications at 703-872-9306, in order to expedite the handling of such correspondence as amendments under 37 CFR 1.312; information disclosure statements, and formal drawings. Sending Post-Allowance papers to Technology Center 1600 will only cause delays in matching papers with the case.

For information concerning status of correspondence sent after receipt of the Notice of Allowance, please contact the Correspondence Branch at (703) 305-8027. The Notice

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of Allowance also has an insert containing contact information on other items, including Issue Fees, receipt of formal drawings and the status of the application.

zt

A handwritten signature in black ink, appearing to be "Z. D.", followed by a horizontal line.